Information Note – Registration of a New Paraquat End-Use Product with a Closed Delivery System in response to the 2015 Special Review (REV2015-14)

3 July 2018

Canada

As part of the special review of paraquat, several additional mitigation measures to further protect human health and the environment were required, as outlined in Re-evaluation Note REV2015-14, *Special Review Decision: Paraquat*. One of the required mitigation measures was to reduce the concentration of paraquat in the only end-use product currently registered in Canada, Gramoxone Liquid Herbicide with Wetting Agent (Registration Number 8661). Consequently, the registration of this product, with the current concentration and packaging, was cancelled and its last date of use (expiry) will be on 31 December 2018.

Following the special review decision, the registrant made an application to register a new end-use product, Gramoxone 200 SL, containing the active ingredient paraquat with a different product delivery system. The end-use product is to be contained only within a closed-system package, used only with a closed-transfer system for mixing/loading activities, and applied only by groundboom. These modifications were submitted as an alternative mitigation to the requirement for a reduced paraquat concentration in the registered end-use product outlined in REV2015-14. This application was assessed by Health Canada to determine if it addresses the human health concerns identified in the special review (potential risk of health effects as a result of accidental exposure in occupational settings).

Health Assessment of the New Closed-Transfer Packaging System.

For Gramoxone 200 SL containing paraquat, a risk assessment was conducted, comparing the potential occupational exposure from the new closed-transfer packaging system for groundboom applications with the exposure from the existing open-pour mixing/loading system currently registered. This risk assessment demonstrated that the closed system reduces mixer/loader exposure and addresses the concern regarding potential risk of health effects as a result of accidental exposure in occupational settings which triggered the requirement for reducing the concentration of paraquat in the end-use product. No health risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label of Gramoxone 200 SL.

Conclusion

Health Canada's Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the registration of Gramoxone 200 SL (Registration Number 33125). This end-use product is to be contained within a closed-system package only, and to be used with a closed-transfer system for groundboom applications only. As this new product addresses the human health concern regarding potential risk of health effects as a result of accidental exposure in occupational settings, a reduced concentration of paraquat in the end-use product is no longer required.